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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,197	10/26/2001	Martin J. Wensley	509032001500	1701
37485	7590	09/21/2006	EXAMINER	
SWANSON & BRATSCHUN, L.L.C 1745 SHEA CENTER DRIVE, SUITE 330 HIGHLANDS RANCH, CO 80129			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/057,197

Applicant(s)

WENSLEY ET AL.

Examiner

Darwin P. Erez

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10, 11, 39-43, 48, 124-130 and 135-180 is/are pending in the application.
- 4a) Of the above claim(s) 39-43, 156-168, 174, 176, 178 and 180 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 10, 11, 135-155, 169-173, 175, 177 and 179 is/are allowed.
- 6) ☒ Claim(s) 48 and 124-130 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/13/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species II in the reply filed on 6/23/06 is acknowledged. The traversal is on the ground(s) that the non-elected embodiments have been previously allowed. This is not found persuasive because the indication of allowable subject matter for claims 10, 49, 48 and 124 is withdrawn and that the mode of operation of each specific heater is different and unique from the other heaters.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 39-43, 156-168, 174, 176, 178 and 180 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/23/06.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over 5,146,915 to Montgomery.

Montgomery teaches a method of generating an aerosol comprising the steps of heating a physiologically active compound via heaters **32** located within a heating-vaporization zone having a restricted cross-sectional area. The heaters is said to be contained within a restricted cross-sectional area because the vaporizer housing **1** has a definitive shape and that the applicant has not provided any additional structural limitation to further define what constitutes as a "restricted cross-sectional area". The vapor generated by the heaters are mixed with a carrier gas (col. 2, lines 8-10) to form a ratio of vapor to carrier gas when a stable concentration of particles in the gas is reached (the heater is energized first prior to opening the inlet for the carrier gas). Montgomery teaches a control valve **28** that is capable of maintaining a pressure drop through the heater at a gas flow rate no greater than 10 inches of water, which depends on the position of the control valve, but is silent with regards to any specific teaching for this limitation. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the pressure drop at less than 10 inches of water, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, the pressure drop of the gas flow rate is merely dependent upon the position of the control valve **28**, which could allow gas to flow through at a low or high pressure.

6. Claims 124-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,388,574 to Ingebrethsen in view of US 5,894,841 to Voges.

(claim 124) Ingebrethsen teaches a method of generating aerosol comprising the steps of depositing a physiologically active compound onto a mesh screen carrier (col. 4, line 32); and heating the compound by passing a current across the carrier to vaporize the compound (col. 4, lines 21-33). Ingebrethsen is silent with regards to the method comprising the step of mixing the vapor with the carrier gas in a ratio to form a desired particle size when a stable concentration of particles in the gas is reached. However, Voges teaches that the droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity (col. 1, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Ingebrethsen to include the step of mixing the resulting vapor with a carrier gas in a ratio to form a desired particle size since Voges teaches that it is well known in the art to control the particle size since the particle size is a function of the delivered pressure and velocity of the carrier gas, i.e., controlling the pressure and velocity of the carrier gas will alter the ratio of vapor to carrier gas. Furthermore, constant application of the same pressure and velocity of the carrier gas would produce aerosol with the same particle size, thus producing a stable concentration (inherent via the function of the pressure and velocity of the carrier gas in relation to the vapor).

(claims 125-127) Ingebrethsen teaches that the mesh can vary in size and configuration (col. 4, lines 29-30). Therefore, it would have been obvious to one of ordinary skill in the art to provide a single mesh screen or a plurality of mesh screens, or

a mesh screen having 200 mesh, because Ingebrethsen teaches that any mesh screen configuration is usable in his invention. Thus, choosing a specific number of mesh screens would be a mere obvious design choice to one of ordinary skill in the art since either configuration would provide the same function of providing heat.

(claim 128) Ingebrethsen discloses a battery power source but is silent with regards to a capacitor power source. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a capacitor power source since the examiner takes Official Notice of the equivalence of a battery power source and the capacitor power source for their use as a source of energy in the art and that the selection of any of these known equivalents would be within the level of ordinary skill in the art.

(claim 129 and 130) Ingebrethsen discloses the claimed invention except for the current being passed for the recited period of time. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pass current for the recited period of time, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

***Allowable Subject Matter***

7. Claims 10, 11, 135-155, 169-173, 175, 177 and 179 are allowed.
8. The following is a statement of reasons for the indication of allowable subject matter:

9. The prior art of record fails to teach or render obvious a method of generating aerosol for inhalation of a patient, comprising the steps of, inter alia, the ratio of vapor to gas is controlled by regulating the gas flow rate within a desired range and wherein the flow rate is monitored and heating of the compound is stopped if the flow rate is not maintained within the desired range.

### ***Response to Arguments***

10. The indicated allowability of claims 48 and 124-130 is withdrawn in view of the newly discovered reference(s) to Montgomery and Ingebrethsen. Rejections based on the newly cited reference(s) is presented above.

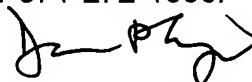
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Darwin P. Erez  
Examiner  
Art Unit 3731

de